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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1000512848
Facility ID: 124545
Inspection ID #1245450015

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

03-BLT-20

July 14, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Cathy Chavis, Office Manager
Breast Imaging at Mercy Medical Center
301 Saint Paul Place
Baltimore, Maryland 21202

Dear Dr. Chavis:

We are writing to you because on June 24, 2003, a representative of the State of Maryland, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following violations of the MQSA, 42 U.S.C. § 263b(f), at your facility:

- **Level 2 Repeat:** Your facility failed to document that weekly phantom quality control testing was performed for the following weeks:
  - Room 1: 10/27/2002, 12/29/2002
  - Room 2: 10/20/02, 12/29/2002
  - Room 3: 10/20/2002, 10/27/2002, 12/29/2002

  [21 CFR 900.12(e)(2)]

- **Level 2 Repeat:** Your facility failed to specify adequate procedures for collecting and resolving consumer complaints **[21 CFR 900.12(h)]**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 2 Repeat finding indicates that the inspector found a deviation from MQSA standards that may seriously compromise the quality of mammography services offered by the facility, and that the same type of violation was found during a previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, seeking to suspend or revoke your facility's FDA certificate, or seeking a court injunction against further mammography. See 42 U.S.C. 263b(h)-(j).

Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. The specific steps you have taken to **correct** all of the violations noted in this letter;

2. Each step your facility is taking to **prevent the recurrence** of similar violations; and

3. Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Elizabeth A. Laudig, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Lee Bowers
Director, Baltimore District